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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO.      |
|---|-------------|----------------------|---------------------|-----------------------|
| 10/816,252  | 04/02/2004  | David Walter Wright  | 115624              | 8511                  |
| 25944   | 7590        | 09/11/2009           | EXAMINER            |                       |
| OLIFF & BERRIDGE, PLC<br>P.O. BOX 320850<br>ALEXANDRIA, VA 22320-4850 |             |                      |                     | BOWERS, NATHAN ANDREW |
| ART UNIT  |             | PAPER NUMBER         |                     |                       |
| 1797  |             |                      |                     |                       |
| MAIL DATE   |             | DELIVERY MODE        |                     |                       |
| 09/11/2009  |             | PAPER                |                     |                       |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/816,252             | WRIGHT ET AL.       |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | NATHAN A. BOWERS       | 1797                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 03 June 2009.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1 and 3-66 is/are pending in the application.  
 4a) Of the above claim(s) 31-55 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-30 and 56-66 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

|  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____.   | 6) <input type="checkbox"/> Other: _____ .                        |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

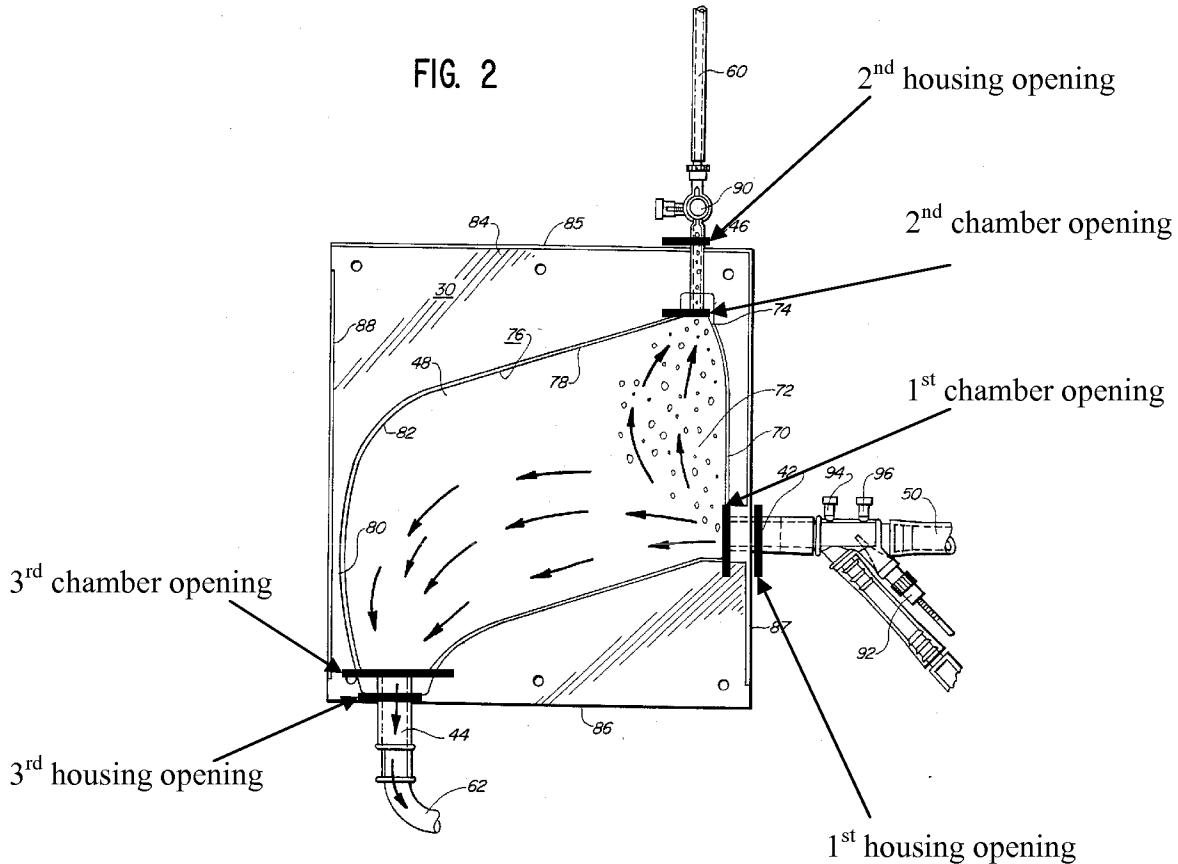
The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1) Claims 1, 3, 4, 10-12, 18, 19 and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Viitala (US 4643713) in view of Oshiyama (US 4976708).

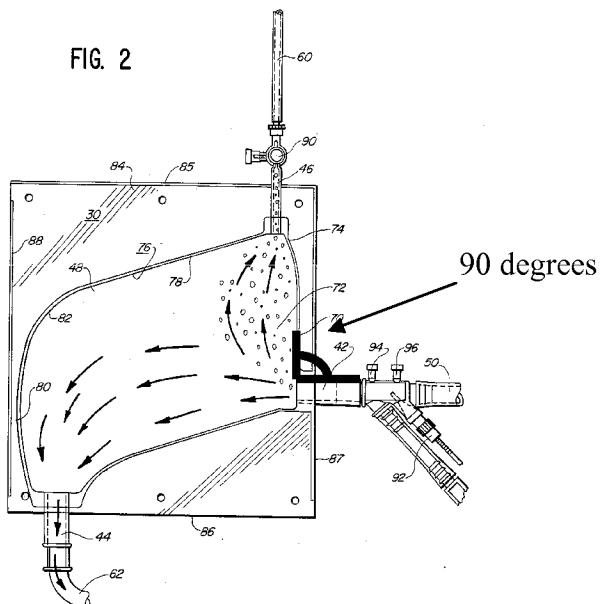
With respect to claims 1 and 3, Viitala discloses an apparatus for separating gas from a liquid path comprising a chamber housing formed by sealing together two plastic sheets (Figure 2:84). A chamber (Figure 2:48) is formed between the sheets and within the chamber housing. This is disclosed in column 3, line 57 to column 4, line 2. The chamber has a top wall (Figure 2:76), sidewalls (Figure 2:70, 80) and a bottom wall. A first chamber opening and a first housing opening serve to allow a liquid and gas to enter the chamber. A second chamber opening and a second housing opening are configured to remove a gas from the chamber, and a third chamber opening and a third housing opening are configured to remove a fluid from the chamber. Column 2, line 58 to column 3, line 15 states that blood moves into the chamber through the first openings, and that air is exhausted from the second openings while air-free blood is removed through the third openings.



A plurality of channels are formed within the housing (between the sealed plastic sheets 84) so that each channel is in fluid communication with a respective chamber opening. Each channel serves to connect a respective housing opening with a corresponding chamber opening. Viitala teaches that no additional structures are positioned within the chamber, and accordingly discloses uninhibited fluid communication between the first, second and third chamber openings.

Although Figure 2 suggests that the second chamber opening is located at the top portion of the chamber, it is not entirely clear whether the second chamber opening is located in the *middle* of the top portion. From Figure 2, it appears that the second

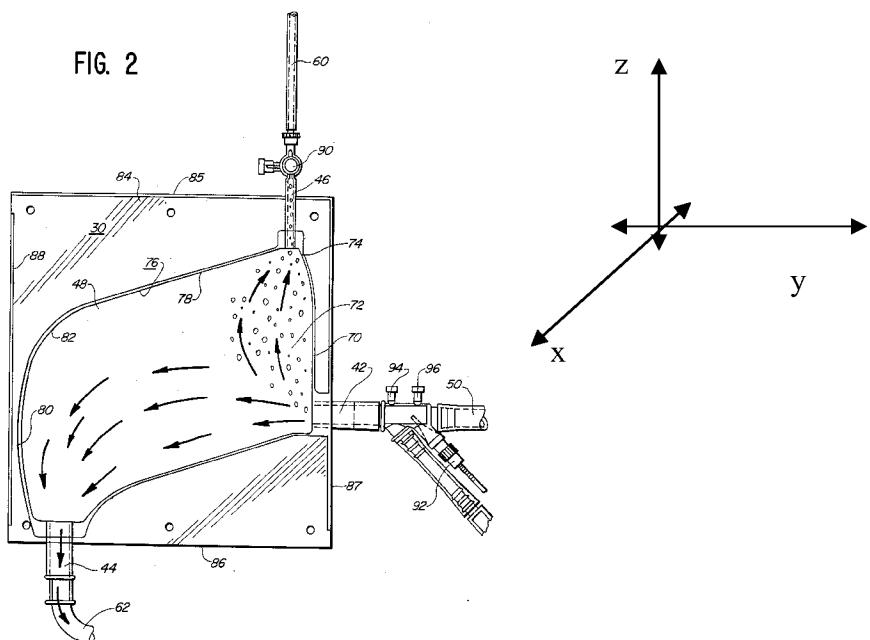
chamber opening is located at one side of the top portion. However, it would have been obvious to ensure that the second chamber opening of Viitala is located in a middle-portion of a top portion. This would represent a mere rearrangement of parts that would not affect the functionality of the device, and instead would only represent a cosmetic design choice. Viitala does not disclose any teachings that require the second chamber opening to be positioned at one side of the top portion. Viitala only states in column 3, lines 22-25 that the sidewall (Figure 2:70) leading to the second chamber opening must be at a sharp right angle with the first chamber opening, but says nothing about the placement of the second chamber opening.



Therefore, one of ordinary skill would have found it obvious to position the second chamber opening anywhere along the top portion of the chamber.

It is additionally noted that second chamber opening is located between (i.e. in the *middle*) of the sheets (Figure 2:84) that form the chamber housing. Therefore, the

second chamber opening could be considered to be formed in a middle portion of the top portion, if the “middle” is defined along the x-axis (rather than the y-axis) – (as defined by Figure below).



Viitala additionally teaches that third chamber opening is at a bottom portion of the chamber. Vittala, however, does not expressly teach that the third chamber opening is at a *middle* portion of the bottom.

Oshiyama discloses an apparatus for separating gas from a liquid path comprising a chamber (Figure 1:12) having a top, bottom and side walls. A first opening (Figure 1:15) allows gas and liquid to enter the chamber, a second opening (Figure 1:18) is configured to allow gas to exit the chamber, and a third opening (Figure 1:17) is configured to allow liquid to exit the chamber. This is taught in column 4, line 41 to

column 6, line 22. Column 5, lines 45-62 state that the third opening is located in a middle portion of the chamber bottom when  $L2/L = 0.5$  (see Figure 1).

Viitala and Oshiyama are analogous art because they are from the same field of endeavor regarding debubbling apparatuses for blood.

At the time of the invention, it would have been obvious to provide the third chamber opening of Viitala at a middle portion of bottom of the chamber rather than to one side. Oshiyama teaches a similar debubbler bag configuration that successfully removes air from a blood stream, wherein the third chamber opening for removing air-free blood is at a middle portion of the chamber bottom. Accordingly, one of ordinary skill would have recognized that a successful gas separating procedure could likewise be completed in the Viitala apparatus if the Viitala third chamber opening was located at the middle of the chamber bottom.

Alternatively, it is additionally noted that the third chamber opening is located between (i.e. in the middle) of the sheets (Figure 2:84) forming the chamber housing in Viitala. Therefore, the third chamber opening could be considered to be formed in a middle portion of the bottom portion, if the “middle” is defined along the x-axis (rather than the y-axis) – (again, see Figure above).

With respect to claims 4, 19 and 24, Viitala and Oshiyama disclose the apparatus in claim 1. As previously set forth above, Viitala indicates that the chamber is located within a housing, and that each housing opening is in fluid communication with the chamber through respective channels. Each channel has a first end at a housing

opening and a second end at a chamber opening. See Figure 2. The channel associated with the first opening operates as an entrance for blood, and the channels associated with the second and third openings operate as exits for air and air-free blood, respectively.

With respect to claim 10, Viitala and Oshiyama disclose the apparatus in claim 1. The debubbler of Viitala further comprises a plurality of connection devices (Figure 2:94, 96) is capable of connecting to either a tube frame, an organ or tissue transporter, a perfusion device, or a diagnostic device. The debubbler is also capable of interacting directly with a blood tube (Figure 2:50) that could in turn be in communication with essentially any organ or tissue device.

With respect to claim 11, Viitala and Oshiyama disclose the apparatus in claim 1. Viitala and Oshiyama each teach that the device is constructed from plastic. Transparent plastic materials are considered to be well known in the art.

With respect to claims 12 and 18, Viitala and Oshiyama disclose the apparatus in claim 3. Viitala further teaches that tubing (Figure 2:60, 50, 64) is connectable to each of the plurality of openings.

With respect to claim 65, Viitala and Oshiyama disclose the apparatus in claim 1. Oshiyama further states in column 5, lines 45-62 that the first chamber opening is located at or near the bottom portion of the chamber when H1/H is approximately 0.

At the time of the invention, it would have been obvious to provide the first chamber opening of Viitala the bottom of the chamber rather than towards the middle. Oshiyama teaches in column 5, lines 45-62 that this fluid opening configuration allows for the successful removal of air from a blood stream. One of ordinary skill would have recognized that a successful gas separating procedure could likewise be completed in the Viitala apparatus if the Viitala first chamber opening was located at the bottom of the chamber.

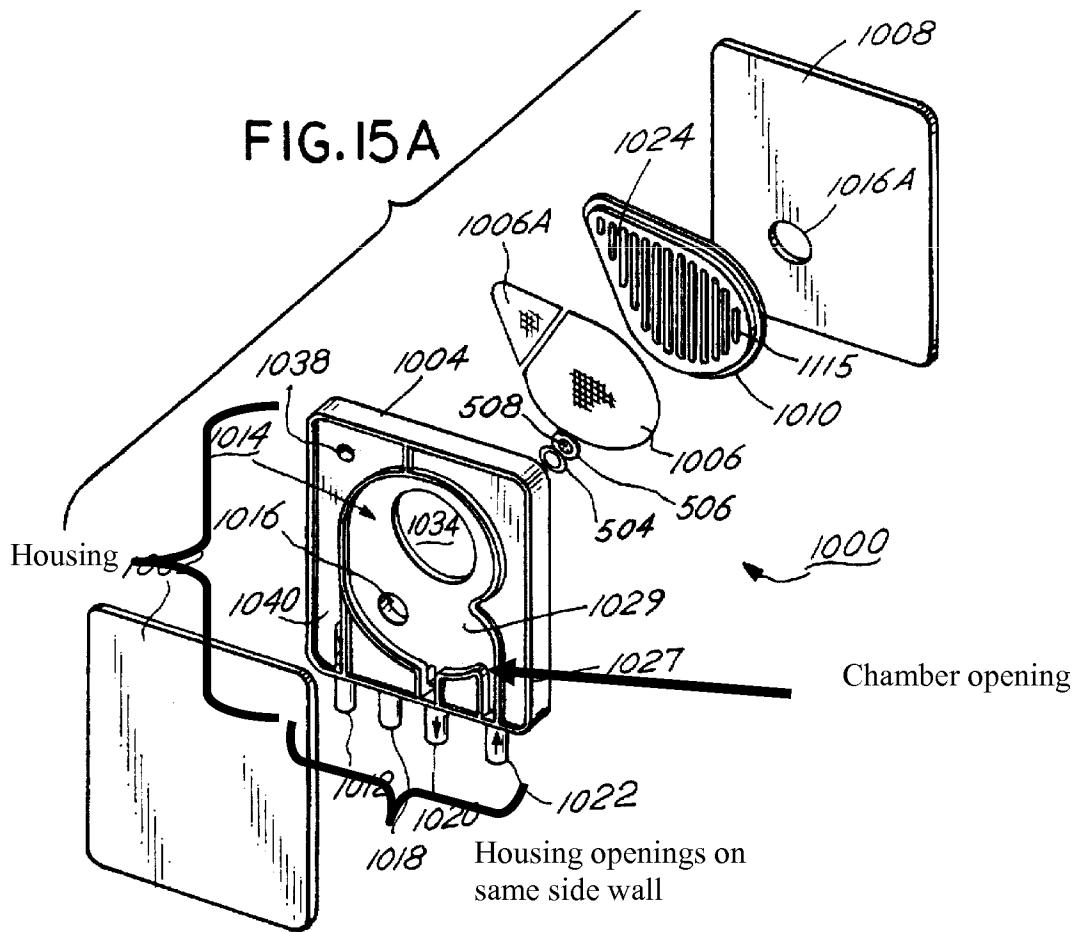
2) Claims 5-9 and 20-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Viitala (US 4643713) in view of Oshiyama (US 4976708) as applied to claims 4 and 19, and further in view of Pawlak (US 5674397).

With respect to claims 5-9, Viitala and Oshiyama disclose the apparatus set forth in claims 4 and 19, however do not expressly indicate the claimed housing opening and channel configurations set forth in Applicant's claims.

Pawlak discloses a debubbler that comprises a chamber housing defining a chamber (Figure 15:1029) capable of holding a liquid and gas. Openings and channels are cut into the sidewalls of the housing in order to allow the ingress and withdrawal of fluid and gas streams. This is disclosed in column 27, line 44 to column 28, line 4. Gas and liquid are separated by a membrane (Figure 15:1006), and degassed fluid is

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removed from one opening (Figure 15:1020) while gas is removed from another opening (Figure 15:1018). As depicted in the annotated Figure 15A below, Pawlak teaches that the housing openings are all located on the same side wall of the housing.



Viitala and Pawlak are analogous art because they are from the same field of endeavor regarding gas-liquid separation systems.

At the time of the invention, it would have been obvious to alter the construction of the Viitala apparatus so that each of the housing openings are located on the same sidewall of the housing. Pawlak teaches that this configuration is well known in the art, and is suitable for the effective removal of gases and liquids. The creation of housing

openings on one side of the Viitala apparatus would merely have required the formation of additional apertures through the top sheet at the end of each channel.

With respect to claims 20-30, Viitala and Oshiyama do not disclose the various channel orientations claimed by Applicant. However, none of these limitations serve to patentably distinguish the instant invention from the cited prior art, because the claim 20-30 limitations merely involve rearrangement of parts that are well known in the art. One of ordinary skill would have readily recognized that the Viitala and Oshiyama channels could be configured so that they are curved, have various vertical sections, and have various horizontal sections. This is primarily because the rearrangement of these parts does not impact the functionality of the device, but rather is instead a simple design choice. Curved channels and straight channels would each serve to remove gas and/or liquid in an equivalent manner. Channels that wrap around the interior of the housing before interfacing with the housing opening would not substantially affect the withdrawal of a liquid or gas, and would not differ in operation than channels that are straight and directly link the chamber opening to the housing opening.

3) Claims 13-17, 56-64 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Viitala (US 4643713) in view of Oshiyama (US 4976708) as applied to claims 12 and 58, and further in view of Sadri (US 5494822).

With respect to claims 13-17, Viitala and Oshiyama disclose the apparatus set forth in claim as set forth in the 35 U.S.C. 103 rejection above, however do not

expressly state that a sensor is provided for detecting gas moving through the first and/or third housing openings.

Sadri discloses a device for transporting and maintaining an organ that comprises a chamber (Figure 1:25) for holding the organ, a fluid supply line (Figure 1:13) and an oxygenator (Figure 1:6). This is disclosed in column 10, line 34 to column 11, line 6. Column 6, lines 11-20 further state that a bubble trap is provided between the oxygenator and the perfused organ. Sensors (Figure 1:14) monitor gas levels of fluid moving from the bubble trap to the organ chamber. Column 11, lines 50-58 state that the flow rate of perfusate flowing into the organ is altered in response to gas level characteristics measured in the fluid. Column 7, lines 40-60 indicate that the operation of the pumping mechanisms and valves regulating the fluid system are controlled in response to measurements made by the gas sensors. Although Sadri does not specifically disclose the use of an ultrasonic gas sensor, ultrasonic gas sensors are considered to be well known in the art. It would have been obvious to use any known sensor in the apparatus of Sadri.

Viitala and Sadri are analogous art because they are from the same field of endeavor regarding culture means.

At the time of the invention, it would have been obvious to equip the apparatus of Viitala with a gas monitoring probe capable of interacting with a control system designed to regulate fluid flow to and from the debubbler in response to detected gas levels. Since the intent of the Viitala device is to remove gas from a blood stream, one

of ordinary skill in the art would have found it obvious to include sensing means capable of determining the efficacy of the system and the extent of gas removal.

With respect to claims 56-64 and 66, Viitala and Oshiyama disclose the apparatus set forth in claim as set forth in the 35 U.S.C. 103 rejection above, however do not expressly state that the debubbler is used in combination with an organ located in an organ transporter.

Sadri discloses the apparatus as previously described above. Sadri teaches the use of a perfused organ (Figure 1:15) positioned within an organ transporter (Figure 1:25). Sadri further teaches in column 6, lines 11-20 that a bubble trap is often required to treat fluid moving through the organ.

At the time of the invention, it would have been obvious to utilize the combination of Viitala and Oshiyama to treat blood moving through an organ located in an organ transporter. Sadri teaches in column 6, lines 11-20 that debubblers are especially applicable to organ perfusion systems because they remove bubbles that could embolize in the organ causing infarction.

### ***Response to Arguments***

Applicant's arguments filed 03 June 2009 with respect to the 35 U.S.C. 103 rejections involving Oshiyama in view of Pawlak have been fully considered and are persuasive. These rejections have been withdrawn. However, a new rejection has been made in view of the combination of Viitala and Oshiyama.

Viitala does not suffer from the deficiencies of the previously cited prior art because Viitala discloses a debubbler in which the interior space is not partitioned by a filter that serves to inhibit fluid communication. Viitala teaches that uninhibited fluid communication is allowed between the chamber openings.

***Conclusion***

This is a non-final rejection.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NATHAN A. BOWERS whose telephone number is (571)272-8613. The examiner can normally be reached on Monday-Friday 7 AM to 4 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Marcheschi can be reached on (571) 272-1374. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nathan A Bowers/  
Examiner, Art Unit 1797